

REMARKS

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.116, are respectfully requested in light of the remarks which follow.

I. Claim Amendments

By the foregoing amendment, claims 58, 66, 68, 69, and 71 have been amended, and claims 59, 60, 62-65, 67, 70 and 72 have been canceled.

Specifically, claim 58 has been amended to recite a method for producing a nonadherent chicken embryonic stem cell line capable of proliferating in a basal medium in the absence of exogenous trophic factors and cytokines, comprising culturing chicken embryonic stem cells with an inactivated feeder comprising mouse fibroblast STO cells in the presence of a particular set of growth factors (the trophic factors SCF, IGF-1 and bFGF; and the cytokines CNTF, IL-6, soluble IL-6 receptor and IL-11) (step (a)), followed by successive withdrawal of the growth factors (step (b)), and high density inoculation into a bacteriological dish (step (c)).

Support for a "chicken" embryonic stem cell line can be found at least at Table 1 on page 4 of the specification.

Support for the production of an embryonic stem cell line that is "capable of proliferating in a basal medium in the absence of exogenous trophic factors and cytokines" can be found throughout the specification, for example at page 10, lines 1-6 (teaching the total withdrawal of "factors allowing the growth" (i.e. "growth factors")); page 14, lines 26-31 (noting that the term "growth factors" includes cytokines); page 16, lines 9-11 (indicating that the nonadherent stem cells obtained via the inventive method can proliferate in "basic

medium"); page 15, lines 34-48 (defining "basic medium" as a medium devoid of exogenous trophic factors and cytokines); page 23, lines 11-19 (noting that all the exogenous factors (trophic factors and cytokines) are removed; and Example 7, at page 29, lines 9-14 (stating that the term "growth factors" is intended to mean trophic factors and cytokines).

Support for the particular trophic factors and cytokines used in at least the first passage (step (a)) can be found at least at page 22, lines 13 to 25 (where the nature and quantity of each of the growth factors (i.e. trophic factors and cytokines) are mentioned; and at page 29, lines 31-32 (where it is taught that the three trophic factors SCF, IFG-1 and bFGF are used at the start of the culture and are necessary). Thus, Applicants have amended the claims to recite the particular combination of growth factors taught in Example 2 (see page 22, lines 12-25).

Support for progressive withdrawal of each of the trophic factors and cytokines (step (b) of claim 58) can be found at least at page 23, lines 11-19.

Applicants note that because a "nonadherent" cell line has been elected, part (c) of claim 58 has also been amended, to more specifically recite a method for obtaining such nonadherent cells (i.e. "high density inoculation of the chicken embryonic stem cells obtained in step (b) onto a bacteriological dish"). Support for this amendment can be found at least in Example 9 at page 30, lines 25-29.

Claim 66 has been amended to recite that the nonadherent embryonic stem cells are nonadherent chicken embryonic stem cells, in accordance with claim 58.

Claim 66 has been further amended by replacing the phrase "free of exogenous growth factors" with the phrase "free of exogenous trophic factors and cytokines," to clarify that the nonadherent embryonic stem cell line produced by the inventive method is capable of

proliferating in absence of all types of growth factors (i.e. trophic factors and cytokines), also in accordance with claim 58.

Claim 68 has been amended to recite that the cells obtained in step (c) of claim 58 have all, rather than "at least one," of the characteristics recited in claim 68. Support for this amendment can be found at least at page 13, lines 27-28; in Example 10 at pages 31-32; and in Example 9 at page 30, lines 36-39.

Claim 69 has been amended to recite that the cells used in step (a) of claim 58 are initially suspended in the same primary medium used in step (a). Support for this amendment can be found at least at page 21, lines 21-25.

Other amendments to the claims have been made to clarify the claim language and bring the claims into better conformance with U.S. patent practice. These amendments are merely editorial in nature and are not intended to change the scope of the claims or any elements recited therein.

The amendments to the claims, including cancellation of claims, have been made without prejudice or disclaimer to any subject matter recited or canceled herein. Applicants reserve the right to file one or more continuation and/or divisional applications directed to any canceled subject matter. No new matter has been added, and entry of the foregoing amendments of the above-identified application are respectfully requested.

II. Response to Claim Objection

Claims 58-72 were objected to for reciting non-elected subject matter.

As noted above, the claims have been amended such that they are directed to a method for producing a "nonadherent chicken embryonic stem cell line" (claim 58).

Accordingly, Applicants respectfully request reconsideration and withdrawal of the objection to the claims.

III. Response to Claim Rejections Under 35 U.S.C. § 112, First Paragraph – Written Description

Claims 58-71 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description (new matter) requirement.

In particular, the Examiner indicated that the specification does not support a range of 12-8% (claim 58); "SC" (claim 59); or "serum-poor medium" (claim 67).

With regard to claim 58, Applicants note that support for the recited range can be found at least at page 21, lines 25-29 and page 22, lines 26-27 where it is indicated that the embryonic stem cells are inoculated into a medium "supplemented with fetal calf serum at an initial concentration of 12 to 8%" (page 21).

Furthermore, claims 59 and 67 have been canceled, rendering this rejection moot as to those claims.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the written description rejections.

IV. Response to Claim Rejections Under 35 U.S.C. § 112, First Paragraph – Enablement

Claims 58-72 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement rejection.

As noted above, claim 1 has been amended to recite a method of producing a nonadherent chicken embryonic stem cell line using an inactivated feeder comprising STO cells, where the initial culture medium comprises certain trophic factors (SCF, IGF-1, and

bFGF) and cytokines (CNTF, IL-6, soluble IL-6 receptor, and IL-11). Applicants submit that the present inventors have demonstrated that the claimed method can be used to produce the desired stem cell line (see, e.g., Example 2 at page 22, lines 12-25 of the specification). Thus, a person of ordinary skill in the art would be able to practice the claimed invention without undue experimentation.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

V. Response to Claim Rejections Under 35 U.S.C. § 102

Claims 58-72 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Pain et al. (Development 122:2339-2348 (1996)).

It is well established that for prior art to be anticipatory, every element of the claimed invention must be disclosed in a single item of prior art in the form literally defined in the claim. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 213 U.S.P.Q. 81, 90 (Fed. Cir. 1986). Applicants submit that the cited reference fails to satisfy this requirement, for at least the following reasons.

To expedite prosecution in the present application, and not to acquiesce to the Examiner's rejection, claim 1, as noted above, has been amended to recite a method of producing a nonadherent chicken embryonic stem cell line using an inactivated feeder comprising STO cells, where the initial culture medium comprises certain trophic factors (SCF, IGF-1, and bFGF) and cytokines (CNTF, IL-6, soluble IL-6 receptor, and IL-11). In addition, the method comprises a step for progressively depriving the medium of each of the trophic factors and cytokines (step (b)), thus producing a cell line that is capable of proliferating in a basal medium in the absence of exogenous trophic factors and cytokines.

Applicants submit that the cited reference does not teach or even suggest the method recited in claim 1.

In particular, the inventors have demonstrated that it is possible to proliferate chicken embryonic stem cells in a basal medium in the absence of exogenous trophic factors and cytokines (such as LIF). For example, page 10, lines 1-6 of the present specification teach “total withdrawal of factors allowing the growth;” page 14, lines 26-31 clarify that the term “growth factors” includes cytokines as well as trophic factors (see also Example 7 at page 29, lines 9-14); page 16, lines 9-11 indicate that the nonadherent stem cells can proliferate in a basic medium (i.e. in the absence of exogenous trophic factors and cytokines as exemplified at page 15, lines 34-38); and page 23, lines 11-19 teach that all of the exogenous factors (including trophic factors and cytokines) are removed. Thus, the present claims recite a method of producing a chicken embryonic stem cell line comprising a step of culturing the cells in the absence of trophic factors and cytokines.

In contrast to the present claims, Pain et al. teach a method of culturing embryonic stem cells in the presence of cytokines, particularly LIF. In fact, the reference teaches that LIF is necessary for proliferating this type of cells.

Since each and every element of Applicant's claimed invention is not taught by Pain et al., such reference fails to anticipate the claims of the present application. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION


From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

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Date: May 22, 2007

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